

# **EXHIBIT A**

# **Convenience Kits Interim Regulatory Guidance**

This document is intended to provide guidance regarding a new premarket notification regulatory strategy for convenience kits. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. Public input on this document was not obtained prior to implementation because it is believed that this guidance presents a less burdensome policy that is consistent with public health.

Premarket Notification (510(k)) Staff  
Program Operations Staff  
Office of Device Evaluation

May 20, 1997

While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration by contacting the Premarket Notification (510(k)) Section at 301-796-5640. For questions regarding the use or interpretation of this guidance, contact the Premarket Notification (510(k)) Section at 301-796-5640.

U.S DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration  
Center for Devices and Radiological Health

## **Convenience Kits Interim Regulatory Guidance**

As part of the Center for Devices and Radiological Health's organizational transformation initiative, the 510(k) Process Reengineering Team has been carefully examining the Premarket Notification (510(k)) Program to insure that it is operating at peak efficiency and that the optimum public health benefit is achieved given the allotted resources.

During the preliminary examination of the requirements and execution of the 510(k) Program, the Team identified a change to the Program that may reduce the regulatory burden for assemblers of convenience kits. Outlined below is a new regulatory approach to be applied to convenience kits which could result in a decrease in the number of 510(k) submissions for these devices and, in so doing, will save ODE review resources. It is estimated that the Office of Device Evaluation (ODE) receives approximately 300 510(k) submissions per year that could be impacted by this regulatory approach.

### **Background**

Under the current regulations, first time marketers of devices must submit a premarket notification and obtain clearance for a device before it can be lawfully introduced into interstate commerce. Assemblers/manufacturers of convenience kits who intend to market these devices for the first time are subject to these requirements.

Many of the kits that have been the subject of 510(k) review are comprised of legally marketed devices that are simply being assembled in kit form strictly for the "convenience" of the purchaser or user, thus the term "convenience kit." During the review of convenience kit 510(k)s, ODE has traditionally focused its efforts on the intended use(s) of the particular type of kit, the device components that are included in the kit, and the impact that any further processing may have on the kit and/or its components. The labeling for these kits tends to be rather basic, identifying the assembler or manufacturer of the particular kit and the intended use(s). Additional processing typically involves affixing the label to the outside packaging of the kit and terminal sterilization of the kit and its components.

### **New Regulatory Approach**

Based on this experience, FDA believes that under certain circumstances premarket clearance for convenience kits may not be necessary to ensure protection of the public health. Accordingly, FDA intends to propose rulemaking to exempt certain, specifically identified convenience kits from the requirement of premarket notification. Until such a rule is in effect, FDA intends to exercise enforcement discretion regarding the requirement for premarket clearance for

convenience kits that conform with the specific limitations regarding intended use, components, and processing described below.

1. **Intended Use** - Using the 510(k) database, ODE has developed the attached list of generic types of kits that the Agency believes represents established intended use(s) for convenience kits and that does not modify the intended use(s) of the individual kit components. FDA recognizes that additional types of kits may currently exist that should be subject to this guidance. Likewise, FDA anticipates that other types of kits may become eligible for consideration in time. Thus, the list may be periodically updated based on the Agency's experience with this new regulatory approach as well as on comments received from interested parties.
2. **Components** - Convenience kits subject to this guidance should only include components that are either: (1) legally marketed preamendments devices, (2) exempt from premarket notification, or (3) have been found to be substantially equivalent through the premarket notification process. The components should be purchased in finished form, i.e., they should be packaged, labeled, etc., consistent with their legal marketing authorization.
3. **Processing** - This guidance only applies in instances where the kit assembler/manufacture concludes that further processing, if any, of the kit does not significantly affect the safety or effectiveness of any of the kit's components. In making this determination, FDA recommends that kit manufacturers follow the procedures described in FDA's guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device." It is the responsibility of each kit assembler/manufacture to carefully consider the impact that any processing may have on the kit's components.

In the past, sterilization has been a focus of the 510(k) review for convenience kits; therefore, kit assemblers should carefully consider the impact of the sterilization process on individual kit components. If the kit's components may be sensitive to further processing, e.g., surgical sutures, the assemblers/manufacturers should take measures necessary to ensure that the components are not adversely affected by the reprocessing procedures.

In summary, FDA intends to exercise its enforcement discretion, i.e. not require 510(k) clearance, for convenience kits of a type matching one of those included on the attached list, consisting of components that have been cleared through the 510(k) process, and where the assembler/manufacture is able to reasonably conclude that any further processing of the kit and its components does not significantly affect the safety or effectiveness of any of its components. Documentation to support each of these determinations should be maintained in the assembler's/manufacture's files in accordance with the Quality System regulation (21 CFR 820) and should be available for FDA review if needed. It should be noted that while FDA intends to exercise enforcement discretion with respect to premarket notification requirements, assemblers/manufacturers of convenience kits are still required to comply with other general controls including registration, listing, prohibition against misbranding, and good manufacturing practices. In the future, FDA intends to propose rulemaking to formally exempt these types of kits from the requirement of premarket notification.

**Limitations**

FDA does not intend to propose regulatory changes relating to drug requirements for convenience kits. For convenience kits that contain components subject to regulation as drugs, the assembler/manufacture should contact the Center for Drug Evaluation and Research, Division of Prescription Drug Compliance & Surveillance, at (301) 594-0101 regarding premarket requirements for the drug components in the kit.

This guidance is not intended to apply to kit 510(k)s that are under the jurisdiction of the Center for Biologics Evaluation and Research. For information regarding kits reviewed by CBER, the assembler/manufacture should contact the Office of Blood Research and Review, Division of Blood Applications, Biologics Devices Branch at (301) 827-3524.

**Effective Date**

This guidance is effective immediately.

## **Types of Convenience Kits**

The attached list of convenience kits was developed based on FDA's database and is organized by medical speciality. For purposes of this document, the terms "kit," "set," and "tray" are considered synonymous. This list may be periodically updated based on the Agency's experience with this guidance as well as on comments received from interested parties.

### **Name of Kit/Tray/Set and Intended Use (if Needed)**

#### **Anesthesiology Devices**

Airway Suction Kit  
Anesthesia Breathing Circuit Kit (Adult & Pediatric)  
Anesthesia Conduction Kit  
Anesthesia Kit  
Arterial Blood Sampling Kit  
Blood Specimen Collection Kit (Excludes HIV Testing)  
Brachial Plexus Anesthesia Kit  
Caudal Anesthesia Kit  
Continuous Brachial Plexus Block Tray  
Custom Anesthesia Tray  
Epidural Anesthesia Kit  
Glossopharyngeal Anesthesia Kit  
Humidifier - Nebulizer Kit  
Laryngoscope Kit  
Nasal Endotracheal Tube Holder Kit  
Nerve Block Tray  
Orotracheal Intubation Guide Kit  
Oxygen Administration Kit  
Regional Anesthesia Kit  
Spinal Anesthesia Kit  
Spinal Epidural Anesthesia Kit  
Tracheal Suction Set  
Tracheobronchial Suction Catheter Kit  
Tracheostomy and Nasal Suctioning Kit  
Tracheotomy Care Kit

## **Cardiovascular Devices**

Angiography/Angioplasty Kit  
Angioscopic Valvulotome Kit  
Cardiac Catheterization Kit  
Cardioplegia Solution Administration Kit  
Cardiopulmonary Bypass Catheter Kit  
Cardiopulmonary Resuscitation Aid Kit  
Cardiovascular Catheter Sheath Introducer Kit  
Cardiovascular Procedure Kit  
Cardiovascular Surgical Instruments Tray  
Catheter Balloon Repair Kit  
Catheter Guide Wire Kit  
Catheter Introducer Kit  
Central Venous Blood Pressure Kit  
Central Venous Catheter Tray  
CT Biopsy Tray  
Digital Angiography Tray  
Endothelial Cell Harvesting Kit  
Laser Blood Flow Kit  
Lead Introducer Kit  
Percutaneous Atrial Catheter Kit  
Percutaneous Sheath Introducer Kit  
Phlebotomy Blood Collection Kit  
Winged Intravenous Catheterization Kit

## **Clinical Chemistry and Clinical Toxicology Devices**

Blood Alcohol Kit (Excludes HIV testing)  
Blood and Urine Collection Kit (Excludes HIV testing)  
Neonatal Blood Collection Kit and Screening Form (Excludes HIV testing)  
Sex Crimes/Sexual Assault/Suspect Evidence Collection Kit (Excludes HIV testing)  
Urine Collection Kit (Excludes HIV testing)  
Urine Transport Kit (Excludes HIV testing)

## **Dental Devices**

Dental Hygiene Kit  
Dental Implant Surgical Tray  
Dental Prophylaxis Kit  
Denture Repair Kit  
Endodontic Kit  
Fixture Mount Kit  
General Purpose Dental Tray  
Gingival Retraction Kit  
Lapping Tool Kit  
Oral Surgery Tray  
Plaque Disclosing Kit  
Prophylaxis Kit  
Restorative Instrument and Component Tray

## **Ear, Nose, and Throat Devices**

Cricothyrotomy Kit  
Ear Irrigation Kit  
Ear, Nose, and Throat Surgical Tray  
Myringotomy Procedure Kit  
Oral Irrigation Kit  
Pierced Ear/Entry Cleaning Tray  
Tracheostomy Cleaning Tray  
Tracheostomy Kit

## **Gastroenterology-Urology Devices**

Anti-Regurgitation Blood Tubing Kit  
Balloon Gastrotomy Tube Kit  
Barium Enema Kit  
Biopsy Needle Kit  
Bladder Irrigation Kit  
Body Fluids Barrier Kit  
Bulb Irrigation Tray  
Catheter Care Tray  
Catheter (Insertion) Tray  
Cholangiogram Catheter Kit  
Continuous Arteriovenous Hemofiltration Catheter Kit  
Declotting Tray



Dialysis Administration Kit  
Dialysis On/Off Kit  
Dialyzer Holder Set  
Dual Lumen Catheter Tray  
Electrosurgical Electrode Kit  
Endoscope Introducer Kit  
Endoscopic Cholangiogram Kit  
Enema Kit  
Enteral Administration Kit (Adult & Pediatric)  
Esophageal Dilator Kit  
Feeding Tube Kit  
Femoral Catheter Kit  
Flexible and Rigid Choledochoscope Kit  
Foley Catheter Kit (Excludes HIV Testing)  
Gastric Colonic Catheter Irrigation Kit  
Gastric Irrigation and Aspiration Kit  
Gastric Lavage Kit (Adult or Pediatric Use)  
Gastro-Urology Biopsy Kit  
Gastrointestinal Tube Kit  
Gastrostomy Guide Wire Placement Kit  
Gastrostomy Jejunostomy Feeding Tube Kit  
Gastrostomy Tube Kit  
Hemodialysis Tray  
Kidney Perfusion Kit  
Laparoscopic Cholangiogram Catheter Kit  
Laparoscopic Gastrostomy Kit  
Laparoscopic Jejunostomy Kit  
Laparoscopy Kit  
Male External Catheterization Kit (Excludes HIV Testing)  
Multi-Lumen Hemodialysis Catheterization Kit  
Nasogastric Feed Tube Kit  
Nasogastric-Gastrojejunal Kit  
Needle Catheter Jejunostomy Kit  
Nephroscope Set  
Non-Balloon Replacement Gastrostomy System  
Ostomy Care Kit  
Percutaneous Endoscopic Gastrostomy Kit  
Percutaneous Replacement Gastrostomy Tube Kit  
Percutaneous Cholangiogram Kit  
Perineal Irrigation Kit  
Peritoneal Dialysis Administration Kit  
Peritoneal Dialysis Tubing Kit  
Personal Erection Kit

Rectal Dilator Kit  
Replacement Gastrostomy Feeding Catheter Tray  
Single Needle with Uni-Directional Pump Kit  
Single Needle (Co-Axial Flow) Dialysis Kit  
Sterile Infant Gavage Kit  
Subclavian Catheter Kit  
Suprapubic Cystostomy Catheter Kit  
Universal Drainage Tray  
Urinary Irrigation Kit  
Urinary Drainage Collection Kit  
Urinary Catheterization Kit (Excludes HIV Testing)

### **General and Plastic Surgery Devices**

Aspiration Tray  
Basic Set-Up Tray  
Bone Marrow Biopsy Tray  
Bowel Kit  
Breast Biopsy/Localization Tray  
Burn Dressing Tray  
Burn Kit  
Cement and Bone Removal Kit  
Cholecystectomy Kit  
Debridement Tray  
Decontamination Kit  
Dressing Change Tray  
First Aid Kit  
Fluid Drainage Tray  
General Purpose Instrument Tray  
General Surgery Tray  
Herniorrhaphy Kit  
Hysterectomy Kit  
Incision and Drainage Tray  
Irrigation Kit (Wounds)  
Laceration Tray  
Laparoscopic Cholecystectomy Kit  
Laparoscopic Sphincterotomy Kit  
Liver Biopsy Kit  
Minor Surgical Procedures Tray  
Operating Room Accessories Table Tray  
Paracentesis Tray  
Pelviscopy Kit

Plastic Surgery and Accessories Kit  
Shave Prep Kit  
Single Use Instrument Tray  
Skin Prep Tray  
Staple Removal Kit  
Sterile Puncture Tray  
Sterilization Wrap Tray  
Suction Catheter Kit  
Surgical Instrument Tray  
Surgical Retractor Kit  
Suture Kit  
Suture Removal Kit  
Thoracic Catheter Insertion Tray  
Tourniquet Kit  
Ulcer Wound Tray  
Vacuum Powered Body Fluid Collection Kit  
Venous Ulcer Kit  
Wound Drainage Kit  
Wound Dressing Kit

### **General Hospital and Personal Use Devices**

Admission Kit (Patient Utensil)  
Anaphylactic Emergency Kit  
Baby Care Kit  
Blood Administration Kit  
Blood Borne Pathogen Response Kit  
Blood Sampling Kit (Excludes HIV Testing)  
Blood Transfusion Kit  
Body Fluid Barrier Kit  
Body Fluid Clean Up Kit  
Body Fluid Disposal Kit  
Bone Marrow Collection/Transfusion Kit  
Buret Administration Intravenous Kit  
Catheter Repair Kit  
Central Venous Catheter Dressing Change Kit  
Chemotherapy Administration Kit  
Chemotherapy Spill Clean-up Kit  
Chest Drainage Kit  
Clean-Up Kit  
Delivery Room Apparel Kit  
Emergency Response Safety Kit

Fever Monitoring Kit  
I.V. Start Kit  
Insect Sting Emergency Kit  
Intra-Arterial Administration Kit  
Intravenous Extension Tubing Kit  
Lumbar Puncture Tray (Adult & Pediatric)  
Medical Procedure Tray  
Microsurgical Instrument Tray  
Mid-Stream Collection Kit  
Mortician's Kit  
O.R. Scrub Prep Tray  
Oral Administration Set  
Parenteral Administration Kit  
Parenteral Supply Kit  
Percutaneous Introducer Kit  
Peripheral Catheter Insertion Kit  
Personal Protection Kit  
Port Introducer Kit  
Prep Kit  
Pressure Monitoring (Air/Gas) Kit  
Sitz Bath Kit  
Snake Bite Kit  
Snake Bite Suction Kit  
Spill Kit  
Survival Kit  
Thermometer Kit  
Thoracentesis Tray  
Ultrasonic Aspiration Biopsy Kit  
Umbilical Catheter Insertion Tray  
Vascular Access Port Kit  
Venipuncture Kit  
Vomitus Clean-Up Kit

### **Neurological Devices**

Endoscopic Shunt Placement Kit  
Endoscopic Ventricular Catheter Placement Kit  
Intracranial Pressure & Temperature Monitoring Kit  
Lumbar Drainage Catheter Kit  
Lymphangiographic Kit  
Myelogram Kit  
Neurological Test Kit  
Neurological Tray

## **Obstetrical and Gynecological Devices**

Amniocentesis Tray  
Breast Pump Kit  
Cervical Smear Kit  
Cesarean Section Tray  
Circumcision Tray  
Culdocentesis Kit  
Cytology Kit  
D&C Tray  
Delivery Kit  
Emergency Obstetrical Kit  
Endometrial Sampling Kit  
Fetal Blood Sampling Kit (Excludes HIV Testing)  
Forensic Evidence Sexual Assault Kit  
Gynecological Laparoscopic Kit  
Labor and Delivery Kit  
Maternity Kit  
Obstetrical Kit  
Obstetrical Anesthesia Kit  
Obstetrical Vacuum Delivery Kit  
Pap Smear Kit  
Paracervical Anesthesia Kit  
Pelvic Exam Kit  
Pudendal Anesthesia Kit  
Seminal Fluid Collection Kit  
Trocar Kit  
Vaginal Examination Tray  
Vasovasostomy Set

## **Ophthalmic Devices**

Eye Tray  
IOL Tray  
Phaco Kit  
Surgical Eye Tray  
Vitrectomy Kit

### **Orthopedic Devices**

Disposable Joint Aspiration/Injection Kit  
Endoscopic Plantar Kit  
Graft Harvesting Kit  
Laparoscopic Bone Anchor Urethropexy Instrument Kit  
Orthopedic Tray  
Pre-Drill Kit for Cartilage Re-surfacing  
Surgical Cannulae & Depth Gauge Kit for Arthroscopic Procedures  
Surgical Kit  
Transtibial Anterior Cruciate Ligament Kit

### **Physical Medicine Devices**

Hand Accessory Kit

### **Radiology Devices**

Arthrogram Tray  
Biopsy Needle Guide Kit  
Dental Tray  
Discography Kit  
MRI Disposable Kit  
Prostate Seeding Kit  
Radiographic Contrast Tray  
Radiology-Diagnostic Kit